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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD JAMES JANDACEK,
WILLIAM RANDALL FRANCIS,
GARY ROBERT KELM, and BRYN HIRD

Appeal 2011-012288
Application 10/699,351
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition comprising a stiffening agent, lipase inhibitor and foam. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Background

"The present invention relates to compositions comprising a stiffening agent, wherein the compositions are useful for stiffening unabsorbed dietary fat and oil present in the gastrointestinal tract, thereby reducing gastrointestinal side effects and separation of these substances from fecal matter" (Spec 1, ll. 13-15).

The Claims

Claims 1, 3, 5-7, and 9-12 are on appeal. Claim 1 is representative and reads as follows:

1. A composition comprising:
   (a) a stiffening agent having a complete melting point of about 33°C or greater which is selected from the group consisting of R-COOR', R-OR', R-CONR'R", R-NR'R", salts thereof, and mixtures thereof, wherein:
      (i) R is selected from the group consisting of alkyl radicals having from about 14 to about 24 carbon atoms, alkenyl radicals having from about 14 to about 24 carbon atoms, alkynyl radicals having from about 14 to about 24 carbon atoms, heteroalkyl radicals having from about 14 to about 24 carbon atoms, heteroalkenyl radicals having from about 14 to about 24 carbon atoms, and heteroalkynyl radicals having from about 14 to about 24 carbon atoms; and
      (ii) R' and R" are each, independently, selected from the group consisting of hydrogen, alkyl radicals, alkenyl radicals, alkynyl radicals, heteroalkyl radicals, heteroalkenyl radicals, and heteroalkynyl radicals; and
   (b) a lipase inhibitor; and
   (c) a non-digestible, non-absorbable, open-celled high internal phase emulsion (HIPE) foam.

The issue

The Examiner rejected claims 1, 3, 5-7, and 9-12 under 35 U.S.C. § 103(a) as obvious over de Smidt,[1] Maeder,[2] and Park[3] (Ans. 6-8).

The Examiner finds that de Smidt teaches "a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition as recited by instant claim 1 is a stiffening agent) . . . wherein R is (12-20 carbon atoms; see col. 3, line 60), having a melting point of 37°C (i.e., greater than 33°C and (ii) a lipase inhibitor" (Ans. 6). The Examiner finds that Maeder teaches "a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid" (Ans. 7). The Examiner finds that Park teaches "a non-digestible, non-absorbable, open-celled HIPE foam compositions and methods of orally administering said forms compositions for the treatment of obesity" (Ans. 7).

The Examiner finds it obvious "to expand the teachings of de Smidt to include a non-digestible, non-absorbable, open-celled HIPE foam in the drug delivery foam compositions disclosed by Park et al. for formulation of a composition for reducing fat absorption or for treating obesity, as taught by de Smidt" (Ans. 7).

Appellants contend that "de Smidt does not teach or suggest the stiffening agent as recited in independent claim 1. Maeder fails to remedy the deficiency of de Smidt and teaches only fatty acids and fatty acid salts,

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[1] de Smidt et al., US 6,703,369 B1, issued Mar. 9, 2004.
[2] Maeder et al., US 6,730,319 B2, issued May 4, 2004.
[3] Park et al., US 5,750,585, issued May 12, 1998.

particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor" (App. Br. 4)

Appellants contend that "de Smidt, Maeder, and Park do not teach or suggest a non-digestible, nonabsorbable, open-celled high internal phase emulsion (HIPE) foam as recited in claim" (App. Br. 4). Appellants contend that "the hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one *hydrophilic* olefin monomer compound. The hydrogels of Park are not formed from an emulsification process using hydrophobic monomers. . . .Thus, the compositions of Park and the present invention are not the same" (App. Br. 4).

Appellants contend that the ordinary artisan "would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to non-liquid with the present invention" (App. Br. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that de Smidt, Maeder, and Park render the composition of claim 1 obvious?

Findings of Fact

1. de Smidt teaches that "[l]ipase inhibitors include lipstatin and orlistat. . . . Its use for the control or prevention of obesity and hyperlipidemia is described" (de Smidt, col. 1, ll. 10-17).

2. de Smidt teaches a "pharmaceutical composition comprising at least one inhibitor of lipases and at least one fatty acid ester of polyols,

characterized in that the fatty acid ester has a melting point above the body temperature, e.g., >37°C." (de Smidt, col. 2, ll. 44-48).

3. de Smidt teaches that the "term 'glyceride ester' refers to an ester of glycerol. According to the present invention, an ester may contain one to three, preferably one or three C_{12} to C_{20} fatty acid(s) moieties per glycerol moiety" (de Smidt, col. 3, ll. 58-61).

4. de Smidt teaches that the "fatty acid moieties in the fatty acid ester of the polyols have, independently from each other, twelve or more carbon atoms, preferably twelve to twenty carbon atoms" (de Smidt, col. 3, l. 66 to col. 4, l. 1).

5. de Smidt teaches that the "glyceride ester is present in an amount varying between 0.5 and 90% of the total weight of the composition . . . the lipase inhibitor is present in an amount varying from 1 to 50%, preferably from 5 to 30%, of the total weight of the composition" (de Smidt, col. 4, ll. 38-62).

6. Maeder teaches that "[o]rlistat (tetrahydrolipstatin) is a well known example for a lipase inhibitor. . . . Orlistat is useful in the control or prevention of obesity and hyperlipidemia" (Maeder, col. 4, ll. 48-61).

7. Maeder teaches a "pharmaceutical composition comprising a) a solid pharmaceutically active compound which has a melting point ≥37° C. and b) a fatty acid or a fatty acid salt or a mixture of a fatty acid and a fatty acid salt, and c) optionally additional pharmaceutically acceptable excipients" (Maeder, col. 3, ll. 31-38).

8. Maeder teaches that "the fatty acid or a fatty acid salt or the mixture of a fatty acid and a fatty acid salt may be selected from . . . the

group of a consisting of lauric acid, myristic acid, palmitic acid, stearic acid, arachidic acid and behenic acid" (Maeder, col. 5, ll. 37-43).

9. Park teaches that

> the hydrogel foams can be used to control the appetite of healthy people who desire to reduce the volume of food they take. The presence of bulky hydrogel foams will reduce the space in the stomach and thus the amount of food that can be ingested. The extended presence of hydrogel foams in the stomach will slow down the emptying of food into the intestine. Thus, the hydrogel foams of the present invention can also be used as a therapy for obesity.

(Park, col. 15, ll. 22-30).

10. Park teaches that "hydrogel foams of the present invention are prepared by introducing a gas into an monomer solution comprising at least one hydrophilic olefin monomer compound, about 0.1 to about 10% by weight of a multiolefin-functional crosslinking agent and a surfactant, during polymerization (Park, col. 3, ll. 50-54).

11. Park teaches that the "polymerization reaction is conducted in an aqueous solution; however nonaqueous solvents, preferably water miscible non-aqueous solvents . . . can also be used to form the hydrogel foams" (Park, col. 3, ll. 55-60).

12. Park teaches that "hydrogel foam can be prepared that is bioerodible and will disintegrate upon exposure to enzymatic digestion" (Park, col. 4, ll. 63-64).

13. The Specification teaches that "polymeric foams useful herein are prepared by polymerization of the oil phase of certain water-in-oil

emulsions having a relatively high ratio of water phase to oil phase, commonly known in the art as 'HIPE.'" (Spec. 23, ll. 20-22).

14. The Specification defines an HIPE foam, teaching that as "used herein, a polymeric foam material which results from the polymerization of such emulsions is referred to herein as a 'HIPE foam'" (Spec. 23, ll. 22-23).

Principles of Law

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).

"Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Analysis

Appellants contend that "the hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one *hydrophilic* olefin monomer compound. The hydrogels of Park are not formed from an emulsification process using hydrophobic monomers. . . . Thus, the compositions of Park and the present invention are not the same" (App. Br. 4).

The Examiner responds that Appellants' argument that the "hydrogels of Park are not formed from an emulsification process using hydrophobic monomers is found not persuasive because how Park formulates or makes

the open celled high internal phase emulsion bears no relevant to the issue here" (Ans. 10). The Examiner contends that the "claims are not directed to a process of making a HIPE but to using a HIPE, how it is prepared plays no role in this rejection and the Board should not consider Appellant's argument" (Ans. 10).

We find that Appellants have the better position. Claim 1 requires a "high internal phase emulsion (HIPE) foam". The Specification teaches that "polymeric foams useful herein are prepared by polymerization of the oil phase of certain water-in-oil emulsions having a relatively high ratio of water phase to oil phase, commonly known in the art as 'HIPE.'" (Spec. 23, ll. 20-22; FF 13). The Specification then defines a HIPE foam, teaching that as "used herein, a polymeric foam material which results from the polymerization of such emulsions is referred to herein as a 'HIPE foam'" (Spec. 23, ll. 22-23; FF 14).

Thus, in order to satisfy the requirement in claim 1 for a HIPE foam, the foam must be identical to a foam which results from the polymerization of a water-in-oil emulsion (FF 13-14).

The Examiner asserts that "Park et al. teach a non-digestible, non-absorbable, open-celled HIPE foam compositions" (Ans. 7). However, a review of Park does not bear out this assertion, since Park never teaches the use of an emulsion, but rather only teaches the use of water miscible agents (FF 10-11). Thus, the foam of Park is formed from different starting materials than the instantly claimed foam (FF 10, 11, 13, 14).

In order to properly invoke the inherency doctrine, the Examiner must provide evidence or reasoning to suggest that the product being claimed is

necessarily identical to the product of the prior art, and that the products are identical insofar as shown by the available evidence. *MEHL*, 192 F.3d at 1365. Here, the Examiner has failed to provide any evidentiary basis or scientific reasoning which would demonstrate that the gas blown aqueous foam of Park is structurally identical to the HIPE foam claimed, where the HIPE foam is composed of a polymerized emulsion. The evidence of record in Park and the Specification suggests that these are different chemical compositions composed of different components which result in different foams, the claimed HIPE foam and Park's foam which is not an HIPE foam (FF 10, 11, 13, 14).

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that de Smidt, Maeder, and Park render the composition of claim 1 obvious.

SUMMARY

In summary, we reverse the rejection of claims 1, 3, 5-7, and 9-12 under 35 U.S.C. § 103(a) as obvious over de Smidt, Maeder, and Park.

REVERSED

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